REMARKS

Reconsideration of this application is respectfully requested. Petition is hereby made for a three-month extension of time to respond to the outstanding Office Action mailed October 31, 2006.

In the outstanding Office Action mailed October 31, 2006, the Examiner withdrew from further consideration claims 5-16, 20-55, 61-77 and 80-82 as being drawn to a non-elected species. Accordingly, Claims 1-4, 17-19, 56-60, and 78-79 are currently pending in the application. Upon entry of this Amendment, claims 2-4, 57, 78 and 79 will be cancelled, claims 1, 17-19, 56, 58-60 will be amended, and new claims 83-153 will be added.

In the outstanding Office Action, the Examiner noted that all patents and publications incorporated in the application specification will not be considered unless listed in an Information Disclosure Statement. The patents and published patent applications incorporated in the specification of the present application have now been listed in an Information Disclosure Statement that is being submitted with this Amendment so that such patents and published applications can be considered by the Examiner.

In the outstanding Office Action, the Examiner required the trademarks appearing in the application to be capitalized and accompanied by generic terminology. The specification and claims of the present application have now been amended to capitalize

the trademarks appearing in the application and to have them accompanied by generic terminology.

The Examiner also required the Summary of the Invention be shorter than the Detailed Description. The Summary of the Invention has been amended to make it shorter. The Detailed Description has been amended to include the more detailed description of the invention originally set forth in the Summary of the Invention. Thus, it is believed that no new matter has been added to the application by these amendments.

Because of the extensive nature of the amendments to the application specification to capitalize the trademarks appearing in the application and have them accompanied by generic terminology, shorten the Summary of the Invention and add the more detailed description of the invention originally set forth in the Summary of the Invention to the Detailed Description, a clean copy of the specification, as so amended, is being submitted with this Amendment. (Attachment A)

The Examiner objected to claims 2-4, 17-19, 57-60, and 79 because such claims recite "An implantable constriction device", rather than - - The implantable constriction device - -. Such claims have now been amended to recite - - The implantable constriction device - -, as required by the Examiner. Accordingly, the Examiner's objection to claims 2-4, 17-19, 57-60, and 79 should be withdrawn.

The Examiner also rejected claims 3, 18 and 59 under 35 U.S.C. §112, second paragraph, for containing the trademarks/trade names "Teflon" and "Parylene". Claims 3, 18 and 59 have now been amended to capitalize the trademarks and have them

accompanied by generic terminology. Accordingly, the Examiner's §112 rejection of claims 3, 18 and 59 should be withdrawn.

In the outstanding Office Action, the Examiner rejected claims 1 and 56 under 35 U.S.C. §102(b) as being anticipated by Jakobsson (USP 5,772,903). The Examiner also rejected claims 2-4, 17-19, 57-60 and 78-79 under 35 U.S.C. §103(a) as being unpatentable over Jakobsson in view of Furst (US Pub. No. 2002/0099438). The Examiner's rejections are respectfully traversed.

For a claimed invention to be anticipated by a prior art reference, every element of the claim must be disclosed in the reference. Here, amended claims 1 and 56 are not anticipated by Jakobsson because Jakobsson does not disclose all of the limitations recited in claim 1.

Amended independent claim 1 of the present application recites the following limitations: (a) an elongate non-inflatable composite structure; (b) the composite structure being adapted to externally constrict the stomach or esophagus; (c) a property improving means including at least one layer applied on a base material; and (d) an adjustment means adapted to mechanically adjust the non-inflatable composite structure to either enlarge or restrict the stoma opening. All of these limitations are disclosed in the present application with regard to the descriptions of Figures 1 and 2 of the present application. Corresponding limitations are also recited in amended independent meansplus-function claims 56, 83, 87, 91, 95, 99, 103 and 107.

Jakobsson discloses a hydraulically adjustable constriction device, which lacks the above limitations (a) and (d) recited in claim 1. Jakobsson's adjustable constriction device is shown in Figure 2 of Jakobsson. Regarding Figure 2 of Jakobsson, Applicant believes that numeral 13 in Figure 2 should be 19, and vice versa, which is apparent from the description appearing at column 3, line 55, to column 4, line 12, and from Figure 1. The device comprises a band 11, having a supporting elongated outer wall 13 of a substantially non expansible, and flexible material. The flexible material is preferably made of a reinforced plastic material with a flexibility that allows it to be bent to form a closed loop, with the ends 15, 17 of the outer wall 13 being joined to each other. The band also has an inner wall 19 made of an expansible material, preferably an elastic, soft plastic material or the like. The inner wall 19 is attached to the outer wall 13 to thereby providing an expansible cavity between the walls 13 and 19. One end of a conduit 21. e. g., a tube of silicone rubber, opens into the cavity, while the other end of the conduit opens into an injection port 23 for supplying or draining off fluid to or from, respectively, the cavity. The inner wall of the band 19 may be inwardly expanded from adjacent the outer wall 13 to such an extent that when a band loop has been formed, the opening of the loop will be substantially obstructed. The band 11 loop is disposed around an Esophagus 3, whereupon the upper part of the stomach 1 is pulled up through the band loop and then sutured to a stomach 1 part situated below the restriction, thereby forming a pouch 5 having a very small volume and tunnellating the band 11. The opening of the loop is initially adjusted to have its maximum size just after the operation. As time goes, the

pouch 5 will expand, thereby permitting a corresponding reduction of the loop opening without serious consequences for the patient. The reduction is accomplished by injecting through the injection port 23 an appropriate amount of fluid into the cavity of the band loop.

Turning to the Examiner's rejection of claims 2-4, 17-19, 57-60 and 78-79 under §103(a) as being unpatentable over Jakobsson in view of Furst, for a claimed invention to be obvious over a combination of prior art references, there must be some suggestion, motivation or teaching in the prior art that would have led one of ordinary skill in the art to combine the references to produce the claimed invention. *E.g., Ashland Oil, Inc. v. Delta Resins & Refracs.*, 776 F.2d 281, 293 (Fed. Cir. 1985). The Federal Circuit has identified three possible sources for a motivation to combine references:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the matter claimed. This court has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.

Id. at 1457-58 (Fed. Cir. 1998).

In the outstanding Office Action, the Examiner acknowledged that Jakobsson did not disclose a property improving means comprises a coating on a base material at least

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along a side of an elongate composite structure that is intended to contact the stomach or esophagus, the coating having better aggressive body fluid resistant properties and better anti-friction properties than the base material, the coating being selected from the group consisting of TeflonTM, ParyleneTM and a biocompatible metal coating selected from the group consisting of gold, silver and titanium, but that Furst taught such a coating. The Examiner also argued that "[i]t would have been obvious to one of ordinary skill in the art to provide a coating on the elongate structure, as taught by Furst, to Jakobsson [sic] to reduce inflammation, infection, irritation, and/or rejection of the device." 10/31/06 Office Action, p. 6.

Given that the present application claims (1) a composite structure for externally constricting a stomach or esophagusa, and not a an expandable stent for use within a body passageway, as taught by Furst, and (2) a coating having better aggressive body fluid resistant properties and better anti-friction properties than a base material included in the composite structure, and not a coating to reduce inflammation, infection, irritation, and/or rejection of the device, as also taught by Furst, it is clear, the Examiner does not, in his \$103 rejection, rely on any of the three possible sources of motivation to combine references identified by the Federal Circuit. Rather, the Examiner is impermissibly using the claimed invention as a blueprint to piece together elements from the cited references in an effort to produce the claimed invention. However, the Federal Circuit has warned against using a claimed invention as a "blueprint" for piecing together elements in the prior art to defeat the patentability of a claimed invention:

As this court has stated, "virtually all [inventions] are combinations of old elements." . . . Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability."

In re Rouffet, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). (Citations omitted). But, even assuming, arguendo, that the Examiner properly combined the cited Jakobsson and Furst references, the resulting combination still would not be the claimed invention given the deficiencies in Jakobsson discussed above.

Furst does not compensate for the deficiency in Jakobsson noted by the Examiner. Furst discloses a stent for expanding a body passageway, in particular a blood vessel. The stent is inserted in a collapsed state into the passageway and then expanded to cause expansion of the passageway. Furst describes various coatings on the stent in paragraph 0017. However, there is no teaching whatsoever in Furst to use the coatings on an elongate non-inflatable composite structure that externally constricts the stomach or esophagus to form a restricted stoma opening. Thus, rejected claims 2-4, 17-19,57-60 and 78-79 are not obvious over Jakobsson in combination with Furst, and the Examiner's rejection of such claims under §103(a) should be withdrawn.

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In view of the foregoing, it is believed that all of the claims remaining in the application, *i.e.*, claims 1-4, 17-19, 56-60 and 78-79, are now in condition for allowance, which action is earnestly solicited. If any issues remain in this application, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

NIXON & VANDERHYE P.C.

 $\mathbf{R}\mathbf{v}$

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